COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26/03/2001
C(2001) 794

NOT FOR PUBLICATION

COMMISSION DECISION
of 26/03/2001
amending the marketing authorisation for the
medicinal product
"Pegintron - Peginterferon alfa-2b"
for human use

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ONLY THE FRENCH AND THE DUTCH TEXTS ARE AUTHENTIC.

(Text with EEA relevance)

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products,[1] as amended by Commission Regulation (EC) No 649/98,[2]

Having regard to Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93,[3] and in particular Article 8(3) thereof,

Having regard to the application to amend the marketing authorisation issued by Commission Decision on 25 May 2000 concerning the medicinal product "Pegintron - Peginterferon alfa-2b" entered in the Community register of medicinal products under No EU/1/00/131/001-030, submitted on 28 July 2000 under Article 6(1) of the above-mentioned Commission Regulation,

Having regard to the favourable opinion of the European Agency for the Evaluation of Medicinal Products, delivered on 14 December 2000 by the Committee for Proprietary Medicinal Products,

Whereas:

(1) Medicinal product "Pegintron - Peginterferon alfa-2b" meets the requirements of Council Directives 65/65/EEC,[4] 75/318/EEC[5] and 75/319/EEC,[6] as last amended by Directive 93/39/EEC.[7]

(2) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use.

(3) Decision C(2000)1407 of 25 May 2000 authorising the placing on the market of the medicinal product "Pegintron - Peginterferon alfa-2b" should therefore be amended,

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1 OJ L 214, 24. 8. 1993, p. 1.
2 OJ L 88, 24.3.1998, p. 7.
3 OJ L 55, 11.3.1995, p.15.
4 OJ 22, 9.2.1965, p. 369/65.
5 OJ L 147, 9.6.1975, p. 1.
6 OJ L 147, 9.6.1975, p. 13.
7 OJ L 214, 24.8.1993, p. 22.

HAS ADOPTED THIS DECISION,

Article 1

Decision C(2000)1407 is hereby amended as follows:

(a) Annex I (summary of product characteristics) is replaced by Annex I to this Decision;

(b) Annex IIIB(package leaflet) is replaced by Annex II to this Decision.

Article 2

This Decision is addressed to SP Europe, 73, rue de Stalle/Stallestraat 73, B-1180 Bruxelles/Brussel, Belgique/België.

Done at Brussels, 26/03/2001

For the Commission

Erkki Liikanen

Member of the Commission